ULTRA-LOW SULFUR DIESEL IMPLEMENTATION WORKSHOP

A Quality System for Fuels Laboratories

Richard Chapman
BP Global Fuels Technology

November 15-16, 2004

bp

Five Primary Activities for Effective Laboratory Quality Assurance Programs

1. Monitor test method precision and stability through QC sample testing
2. Monitor test method accuracy
3. Periodically evaluate System Performance (i.e., precision, bias)
4. Proficiency Testing (e.g., ASTM crosscheck program
5. Validation or verification (section 7.7 in D 6299)

bp

ASTM Standard Practices & Guides

- **D 6299: Standard Practice for**

  Applying Statistical Quality Assurance Techniques to Evaluate Analytical Measurement System Performance

- **D 6792: Standard Guide for**

  A Quality System in Petroleum Products and Lubricants Testing Laboratories

bp

Summary of ASTM D 6299 Practice

1. QC samples and check standards are regularly analyzed by the measurement system. Control charts and other statistical techniques are presented to screen, plot, and interpret test results in accordance with industry-accepted practices to ascertain the in-statistical-control status of the measurement system.

bp

Summary of ASTM D 6299 Practice - continued

2. **Statistical estimates of the measurement system precision and bias are calculated and periodically updated using accrued data.**
3. **As part of a separate validation audit, QC samples and check standards may be submitted blind or double-blind and randomly to the measurement system.**

bp

ASTM D 6299 Analysis Process

- Convert results to pre-treated data
- Visually look for “bad” data
- Plot and look for unusual patterns
- Test data for normality
- Set up and use control charts
- Evaluate precision
- Evaluate bias
- Verify lab performance

bp

ASTM D 6299 Run Charts

- **A run chart is a plot of results in chronological order that can be used to screen data for unusual patterns:**

  - continuous trending in either direction
  - unusual clustering
  - cycles

bp

Use Control Charts

- **Set up I and MR charts**
  - **I = individual observation**
  - **MR = moving range (plot of sequential range of two values)**
- **The moving range chart provides information independent of the average value.**
- **An MR chart can go out of control even though the I chart is in control.**
- **We don't need a control chart if we don't take action based on the chart.**

bp

ASTM D 6792 Scope

- The D 6792 Guide covers the establishment and maintenance of the essentials of a quality system in laboratories engaged in the analysis of petroleum products and lubricants.
- The D 6792 Guide is designed to be used in conjunction with Practice ASTM D 6299.
- D 6792 contains a checklist for investigating the root cause of unsatisfactory analytical performance.

bp

ASTM D 6792 Checklist

- **An extensive, user-friendly Laboratory Quality System assessment checklist is being balloted as an appendix to D 6792.**

1. Quality Assurance System
2. Test Methods
3. Sample Management
4. Calibration
5. Maintenance
6. Quality Control Program
7. Bias Management and Proficiency Evaluations
8. Data Management
9. Training
10. Assessments
11. Corrective and Preventive Actions
12. Customer Interactions
13. Continuous Improvement

bp

Laboratory Quality System Assessment Checklist (being balloted)

Laboratory: _____ **Date:**_____

	Requirements	Yes/No	Assessor Comments
1.0	**QUALITY ASSURANCE SYSTEM (QAS)**		
1.1	A quality system is established and maintained. (5.1)	☐ **Yes** ☐ **No**	
1.2	The quality system includes stated objectives in the following areas: (5.1) • Laboratory's adherence to test method requirements • Calibration and maintenance practices • Quality control program. • Continuous improvement goals • Meeting customer requirements	☐ **Yes** ☐ **No**	
1.3	The quality system has documented processes for: (5.4) • Sample management • Data and record management • Producing accurate, reliable, and properly represented test results • Audits and proficiency testing • Corrective and preventive action • Ensuring that procured services and materials meet the contracted requirements • Ensuring that personnel are adequately trained to obtain quality results.	☐ **Yes** ☐ **No**	
1.4	Management has appointed a representative to implement and maintain the quality system in the laboratory. (5.2)	☐ **Yes** ☐ **No**	
1.5	Laboratory management reviews the adequacy of the quality system and the activities of the laboratory for consistency with the stated quality objectives at least annually. (5.3)	☐ **Yes** ☐ **No**	

bp